

### **REMARKS**

Favorable reconsideration and allowance of the present application is respectfully requested.

Currently, claims 62-80, including independent claim 62, are pending in the present application. Independent claim 62, for instance, is directed to a system for conducting a lateral flow assay to detect the presence or quantity of an analyte in a sample. The system comprises (a) a lateral flow membrane strip comprising a detection zone, wherein upon application, the sample is capable of traversing through the membrane strip to the detection zone and (b) reading device. The reading device includes the following components:

(1) a "housing" within which is contained an electromagnetic radiation source and a sensor capable of detecting the intensity of electromagnetic radiation; and

(2) a "light barrier structure" positioned adjacent to an exterior surface of the housing. Notably, the light barrier structure defines a receiving port between a top plate and bottom plate for insertion with the membrane strip. Further, the *bottom plate* of the light barrier structure *defines a region through which electromagnetic radiation from the source is capable of passing* before contacting the lateral flow membrane strip. The *region approximates the size of the detection zone*.

In the embodiment shown in Figs. 3-4 of the present application, for instance, the bottom plate 56 and top plate 50 define a receiving port 53 through which the lateral flow membrane strip may be inserted. Upon insertion, light generated by a source is capable of passing through an aperture 54 to contact the strip. Light reflected by the strip may also pass through the aperture 54. By ensuring that the size of the aperture

54 does not substantially exceed the size of the detection zone, the level of noise produced by radiation reflected from other parts of the membrane strip may be minimized. Furthermore, by limiting the aperture size in this manner, the chance of stray or ambient light leaking past the light barrier structure and reaching the sensors of the reading device is reduced. It has therefore been found that the closer the size and/or shape of the aperture corresponds to the size of the detection zone, the higher the signal to noise ratio that can be achieved by the reading device, and the more sensitive will be the reading device.

In the Office Action, independent claim 62 was rejected under 35 U.S.C. §102(b) as being anticipated by EP0308770 or U.S. Patent No. 4,833,088, both to DeSimone, et al.<sup>1</sup> DeSimone, et al. describes a measurement device having a snap action slide assembly that receives a reagent strip in an open position and then loads the strip into a measurement position wherein the strip is aligned with the read head of the device. Ambient light blocking is achieved by movement of an arm relative to the reagent strip upon closing the slide.

In stark contrast, as noted above, the problem addressed by the present claims is how to provide an improved lateral flow assay reading device in which the signal to noise ratio of light reflected from the membrane strip is maximized while avoiding the leakage of ambient light around the detection zone during measurement. This is achieved not only by the receiving port providing a light barrier structure but, additionally and advantageously, by the light aperture itself being sized to match the detection zone

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<sup>1</sup> EP0308770 is the European counterpart to U.S. Patent No. 4,833,088.

and thereby to prevent ambient light leakage. Such an arrangement is neither disclosed nor suggested by DeSimone, et al.

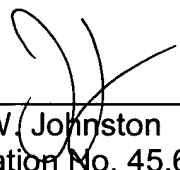
Claims 26-50 were also provisionally rejected in the Office Action under the judicially created doctrine of obviousness-type double patenting in view of copending applications 10/013,973, 10/026,415, and 10/084,763. In response, Applicants agree to submit terminal disclaimers, to the extent necessary to obviate this rejection, at such time that the present application is otherwise deemed in condition for allowance.

It is believed that the present application is in complete condition for allowance and favorable action is respectfully requested. Examiner Alexander is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully submitted,

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